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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,731	05/11/2001	Apollon Papadimitriou	20619	6504

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HOFFMANN-LA ROCHE INC.  
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/853,731

**Applicant(s)**

PAPADIMITRIOU, APOLLON

**Examiner**

Chih-Min Kam

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 13-17, 19, 23-36, 38-42, 44, 48-55, 59-61, 67-77 and 83-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-25 and 83-89 is/are allowed.
- 6) ☒ Claim(s) 1, 13-17, 19, 26, 38, 44 and 67-76 is/are rejected.
- 7) ☒ Claim(s) 2-11, 27-36, 39-42, 48-55, 59-61 and 77 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-11, 13-17, 19, 23-36, 38-42, 44, 48-55, 59-61, 67-77 and 83-89 are pending.

Applicants' amendment and Declaration of Dr. Appollon Papadimitriou under 37 CFR §1.132 filed on February 17, 2004 are acknowledged. Applicants' response and the Declaration of Dr. Appollon Papadimitriou have been fully considered. Claims 12, 37, 56, 57 and 78-82 have been cancelled, claims 1, 3, 11, 15, 24, 26, 28, 34, 40, 48, 52-55, 60, 61 and 71-77 have been amended, and new claims 83-89 have been added. Thus, claims 1-11, 13-17, 19, 23-36, 38-42, 44, 48-55, 59-61, 67-77 and 83-89 are examined.

### **Objection Withdrawn**

2. The previous objection of claims 3, 28, 56, 57 and 78-82 is withdrawn in view of applicants' cancellation of the claims, and applicant's amendment to the claims in the amendment filed February 17, 2004.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 12, 15, 37, 40, 48-50, 52-55, 60, 61 and 71-77 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claims, and applicant's response at page 19 in the amendment filed February 17, 2004.

#### ***Claim Rejections - 35 USC § 102***

4. The previous rejection of claims 1-4, 6, 7, 9-12, 26-29, 31, 32, 34-37 and 54 under 35 U.S.C. 102(b) as being anticipated by Woog *et al.* (U. S. Patent 4,992,419), is withdrawn in view

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of applicants' cancellation of the claims, applicant's amendment to the claims, and applicant's response at page 20-21 in the amendment filed February 17, 2004.

5. The previous rejection of claims 1-9, 11 and 12 under 35 U.S.C. 102(b) as being anticipated by Zale *et al.* (WO 96/40073), is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claims, and applicant's response at page 21-22 in the amendment filed February 17, 2004.

6. The previous rejection of claims 1-17, 19, 26-42, 44, 51, 59 and 67-70 under 35 U.S.C. 102(e) as being anticipated by Bailon (U.S. Patent 6,583,272 B1), is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claims, Declaration of Dr. Appollon Papadimitriou, and applicant's response at page 22-23 in the amendment filed February 17, 2004.

***Claim Rejections - 35 USC § 103(a)***

7. The previous rejection of claims 1-4, 6, 7, 9-13, 26-29, 31, 32, 34-38 and 54 under 35 U.S.C. 103(a) as being unpatentable over Woog *et al.* (U. S. Patent 4,992,419) in view of Rosen *et al.* (WO 92/06116), is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claims, and applicant's response at page 23-24 in the amendment filed February 17, 2004.

8. The previous rejection of claims 1-4, 6, 7, 9-12, 14-17, 26-29, 31, 32, 34-37, 39-42, 54 under 35 U.S.C. 103(a) as being unpatentable over Woog *et al.* (U. S. Patent 4,992,419) in view

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of Elliot *et al.* (EP 0640619), is withdrawn in view of applicants' cancellation of the claims, applicant's amendment to the claims, and applicant's response at page 23-24 in the amendment filed February 17, 2004.

### ***Claim Objections***

9. Claims 71, 73 and 75 are objected to because of the use of the term " $6.2 \pm 0.2$ ". Use of " $6.2 \pm 0.2$ " is suggested.

### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 19, 26, 44 and 67-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/041,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 19, 26, 44 and 67-76 in the instant application disclose a pharmaceutical composition comprising an EPO glycoprotein product having the in vivo biological activity, wherein the glycoprotein product is a pegylated EPO such as EPO being linked to  $-\text{CO}-(\text{CH}_2)_x-(\text{OCH}_2\text{CH}_2)_m-\text{OR}$ . This is an obvious variation in view of claims 1-16 in the copending application which disclose a conjugate comprising an EPO

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glycoprotein having N-terminal  $\alpha$ -amino group and one poly(ethyleneglycol), where EPO is linked to  $-\text{CO}-(\text{CH}_2)_x-(\text{OCH}_2\text{CH}_2)_m-\text{OR}$ , and a pharmaceutical composition comprising the conjugate. Both the claims of the instant application and the claims of the copending application are directed to a pharmaceutical composition comprising a conjugate of EPO with poly(ethyleneglycol). Claims 1, 19, 26, 44 and 67-76 in present application and claims 1-16 in the copending application are obvious variations of a pharmaceutical composition comprising a conjugate of EPO with poly(ethyleneglycol) having the in vivo biological activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants request this rejection be held in abeyance since neither case currently contains any allowed claims; and MPEP 804 I. B and C states that where the provisional double patenting rejection is the only rejection remaining in an application, then the Examiner should withdraw the rejection and permit the application to issue as a patent, thereby converting the provisional double patenting rejection in the other application into a double patent rejection. Applicants indicate they will consider the propriety of a terminal disclaimer in either the instant application or USSN 10/041,363 depending on which application issues first and on the claims that ultimately be allowed in these applications, which is consistent with MPEP Section 804 (pages 18-19 of the response). The comment has been considered, and the ground of rejection remains until all other issues resolved.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 13-17, 38 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claims 13-17 and 38 are indefinite because the claim is dependent from a cancelled claim, claim 12 or 37.
12. Claim 76 is indefinite as to "poloxamers type 188 in an amount of 0.1 mg", it is not clear what concentration the poloxamers type 188 has since the volume of the solution is not indicated.
13. Claims 2-11, 27-36, 39-42, 48-55, 59-61 and 77 are objected to as being dependent upon a rejected base claim.

***Conclusion***

14. Claims 1, 13-17, 19, 26, 38, 44 and 67-76 are rejected, and claims 2-11, 27-36, 39-42, 48-55, 59-61 and 77 are objected to. It appears claims 23-25 and 83-89 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

*CHK*

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May 7, 2004

*Christopher S. F. Low*  
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